APPLICATION FOR APPROVAL TO USE HUMAN PARTICIPANTS (TCNJ)
(Version 1.0)

1.0 General Information

***Please enter the full title of your research project:**

Sandy and Tamra's Amazing Fake Study!

***Please enter the Study Alias you would like to use to reference the study:**

Fake Study
* This field allows you to enter an abbreviated version of the Study Title to quickly identify this study.

2.0 Add Department(s)

2.1 List all of the departments associated with this study:

Primary Dept?	Department Name
◯	**TCNJ** - TCNJ Department
◯	**TCNJ** - - Psychology

3.0 Assign key study personnel (KSP) access to the study. Please ensure that all training is active for all KSP that are added to this study.

3.1 *Please add a Principal Investigator for the study:

Bireta, Tamra

3.2 If applicable, please select the Research Staff personnel:

A) Additional Investigators

B) Research Support Staff

3.3 *Please add a Study Contact:

Bireta, Tamra

The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The study contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).

3.4 Please select the Designated Department Notification(s) (e.g. Department Chair, Dean or

Supervisor):

Vivona, Jeanine M
Department Chair

Add the name of the individual to be informed of protocol from your Department (e.g. the Department Chair or Dean).

4.0 Research Determination
Do I need to seek IRB approval for my project?

4.1 Does the project involve data relating to human subjects (as opposed to plants, animals or inanimate objects)?

(•) Yes ( ) No

4.2 Is the project solely for educational purposes (as opposed to research purposes*)? Note: Answer "No" if the project is for research purposes* or if the purpose is both educational and research.

( ) Yes (•) No

4.3 Is this a project for which you are seeking Inter-institutional IRB Authorization Agreement for which TCNJ will be the institution relying on an external designated IRB?

( ) Yes (•) No

4.4 Are you using archival data only?

( ) Yes (•) No

5.0 Research Description

5.1 Abstract. Provide an abstract of the proposed research or teaching in language that can be understood by a non-scientist . The abstract should summarize the objectives of this project and the procedures to be used, with an emphasis on what will happen to the subjects.
(Maximum 250 words)

5.2 Objectives: List your research objectives. (Maximum 250 words)

5.3 Research Procedures

Describe the research procedures that will be followed.

5.4 What data will be recorded and how?

5.5 **Will devices, machines, equipment, instruments and/or questionnaires/surveys/interviews be used?**

○ Yes ○ No

5.8 **Does this research involve physiological processes?**

○ Yes ◉ No

5.12 **Will international research or research that includes languages other than English be involved?**

○ Yes ◉ No

5.14 **Does this research involve FDA-regulated drugs, devices or biologics?**

○ Yes ○ No

5.15 **Adequacy of Resources to Protect Subjects**

Investigator (including co-investigators) has sufficient time to conduct and complete the research.

○ Yes ○ No

Adequate and qualified (including experience, training and familiarity with the protocol) staff are available for this research.

○ Yes ○ No

5.16 **Describe other resources needed for the protection of subjects in conducting this research (e.g. participant communication needs, language translation services).**

5.17 **Will this research involve deception?**

○ Yes ◉ No

5.21 **Will the research involve stored data for future use?**

○ Yes ◉ No

5.24 **Will the internet be involved in this research?**

○ Yes ◉ No

6.0 Subject Population

6.1 **Describe the subject population to be included in this research.**

6.2 **Will prisoners be involved in this research?**

○ Yes ◉ No

6.5 **Will children be involved in this research?**

○ Yes ◉ No

6.8 **Will pregnant women, fetuses or neonates be involved in this research?**

○ Yes ◉ No

6.11 **Will this research involve cognitively impaired subjects?**

○ Yes ◉ No

6.14 **Will all of the subjects be fluent in English?**

◉ Yes ○ No

6.15 **Include any special characteristics targeted for inclusion.**

Order Number	Criteria
1	Happy!

6.16 **Include any special characteristics targeted for exclusion.**

Order Number	Criteria
1	Mean!

7.0 Research Setting

7.1 **Choose the settings in which research procedures will be carried out.**

- [x] Home of Participants
- [ ] International Location
- [ ] Multiple Locations
- [ ] Prison
- [ ] School
- [ ] TCNJ
- [ ] Other Institution e.g. Hospital, In Patient Facility
- [ ] Other

Specify Other:

7.3 **List all non-TCNJ sites where the procedures will be carried out.**

For each site, describe the IRB communication with the external site and indicate: whether the site has an IRB, whether the site has granted permission for the research to be conducted, and the contact information for the site.

Please be sure to include the location of the subjects (schools, hospitals, clinics, prisons, unions, etc.) as well.

Please note that a signed permission letter on institutional letterhead is required for most research that is conducted at institutional locations (e.g., schools, hospitals, prisons, etc.) outside of TCNJ. This will be attached to the study via the Initial Review Submission Packet.

8.0 Subject Recruitment

8.1 **Describe how subjects will be recruited for participation in this study.**

8.2 **Attach copies of any proposed flyers, posters, pamphlets, print advertisements, web postings, letters, etc. and any scripts for on air advertisements or phone calls. All recruitment material must be approved by the IRB prior to use. If potential participants are not fluent in English, please upload translations of materials. All items will be attached to the study via the Initial Review Submission Packet.**

8.3 **Will subjects be recruited by searching records (e.g., school records, medical records)?**

- ○ Yes
- ○ No

8.4

Will databases be utilized?

○ Yes ○ No

8.5

Will an advertising company be employed for recruitment purposes?

○ Yes ○ No

8.6

Will physician to researcher referral be utilized for recruitment?

If yes, please be aware that HIPAA regulations prohibit physician-to-physician referral; patients must first be informed of a trial and agree to be contacted before any physician referral can be initiated.

○ Yes ○ No

8.7

Are there any other methods not covered in relation to subject recruitment?

○ Yes ○ No

8.8

Will subjects be offered compensation for participating in the research?

○ Yes ○ No

8.10

Explain how the Investigator has access to a population that would allow recruitment of the required number of subjects.

Please upload any relevant documentation providing consent for recruitment (such as letters from the external institution, unless letter was already uploaded under Research Setting). All additional documents that need to be submitted to the IRB will be attached to the study via the Initial Review Submission Packet.

9.0

Risks & Benefits

The purpose of this section is to determine if subjects will be placed "at risk" -- i.e., exposed to the possibility of physical, psychological, sociological, or other harm as a consequence of any activity proposed in the research project.

9.1

Risk Classification: What is the overall risk classification of the research?

NOTE - *According to HHS Regulations minimal risk means "The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."*

- (•) Minimal
- ( ) Greater than minimal
- ( ) Significant
- ( ) Unknown

9.2 **If the classification is minimal risk, please justify why that category is appropriate.**

9.4 **What precautions have been taken to minimize these risks and what is their likely effectiveness?**

9.5 **Describe other alternative and accepted procedures, if any, that were considered and why they will not be used.**

9.6 **Describe how the research will be monitored to ensure subject safety.**

9.7 **Assess the potential benefits to science and/or society which may accrue as a result of this research.**

9.8 **Are there any benefits which may accrue to the individual subjects in this research?**

( ) Yes ( ) No

10.0 Privacy & Confidentiality

10.1 **Explain provisions to protect privacy interests of subjects. This refers to how investigators will contact subjects and/or access private information from or about subjects during and after their involvement in the research (e.g. time, place, etc. of research procedures).**

10.2 **Will the data collected in the course of the study be considered sensitive data (e.g. mental health, HIV status, SS#, etc.)?**

( ) Yes ( ) No

10.3 **Could any of this data, if disclosed, have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation?**

○ Yes ○ No

Explain:

10.4 **What specific safeguards will be employed to protect confidentiality of data (e.g., coding or removal of identifiers as soon as possible, limitation of access to data, use of locked file cabinets, protection of computer-based data systems, etc.)?**

10.5 **Will data that identifies individual subjects be published or in any way be disclosed to third parties other than project personnel?**

○ Yes ○ No

11.0 Informed Consent

Unless waived by the IRB, informed consent is necessary for all research involving human subjects and must be documented in some manner. The investigator may determine which method would best serve the interest of the subject population, but the IRB reserves the right to require alternative or more stringent means of securing consent.

11.1 **Which of the following apply to this research?**

- ☑ Informed consent will be obtained from all subjects and documented with a signed, written consent form.
- ☐ Informed consent will be obtained from subjects, but no signed consent form will be used.
- ☐ Fully informed consent will not be obtained from all subjects. This includes deception, withholding information, etc.

11.2 **Informed Consent**

Describe how the required information is being presented to subjects (consent form, orally, information sheet, etc.).

11.3 **Describe the circumstances under which consent will be obtained, including where the process will take place.**

11.4 **Who will obtain consent? Describe their experience in obtaining consent from subjects.**

12.0 Conflict of Interest

12.1 **Do any members of the research team or any of their immediate family members have any financial interest in the sponsor of this research and/or in the results of this research?**

○ Yes ◉ No

13.0 Application Complete

13.1 **The application for approval to use human participants is completed. NEXT, you will need to hit Save and Continue in the top right corner so you can complete the Initial Review Submission Packet. This is a short form where you complete your lay summary as well as attach all necessary study documents to the initial submission.**

The College of New Jersey

TCNJ Institutional Review Board

RESEARCH SUBJECT INFORMED CONSENT FORM

Dear Prospective Research Participant:
You are being asked to be a volunteer in a research study. Please read this consent form carefully, and ask as many questions as you like before you decide whether you want to participate in this research study. You may also ask questions at any time before, during, or after your participation in this research. You are encouraged to take your time in making your decision.

GENERAL INFORMATION

Project Title: Memory and Aging

Approved protocol number : 1144-20 **Approval date :** March 13, 2014 **Expiration date:** March 12, 2016

Project sponsor(s): The College of New Jersey
Principal Investigator: Dr. Tamra Bireta, Department of Psychology, Humanities and Social Sciences, The College of New Jersey, P.O. Box 7718, Ewing, NJ 08628; Email: tbireta@tcnj.edu; Telephone: 609-771-3069

PROJECT INFORMATION

1. Purpose of the Research: The purpose of this research is to test different theories of memory by examining how accurately you can remember different types of items (such as letters or numbers).

2. Exclusion/ Inclusion Criteria: You must be at least 60 years old, in good health, and a native speaker of American English.

3. Research Procedures: You may be given a brief hearing and/or vision screening and asked to complete a simple test involving memory for lists of digits and a brief vocabulary test. You will be asked to make judgments about items (e.g., words or numbers) and remember sets of items presented either on a computer screen or over headphones. For the conditions in which you are asked to speak aloud, we will tape record your responses. Your responses will be transcribed, and then the recording will be destroyed. There are different versions of the study, and we plan to have approximately 40 to 80 people participate in each version. The length of participation varies, but typically lasts 30 to 60 minutes.

4. Potential Risks and Discomforts: There are no foreseeable risks for participants.

5. Potential Benefits of the Research: You will have the opportunity to learn more about how memory theories are evaluated and how different factors influence memory.

6. Compensation for participation: You will receive $10 for your participation.

7. Alternative procedures or treatments: N/A

8. Provision for Confidentiality: Any results that are reported will be in group form, and only Dr. Bireta and her research assistants will be able to see your results. Your personal information and results will be kept confidential and will not be released to anyone outside of the lab.

9. Research-related Injury: If there are concerns about the treatment of research participants, contact the Institutional Review Board Chair, Dr. Brett BuSha at busha@tcnj.edu. If you experience psychological discomfort as a result of participation in this study, you may contact Counseling and Psychological Services (CAPS) at (609) 771 - 2247.

10. Contacts for additional information: If you have any questions about the study, you may contact the PI (Dr. Tamra Bireta) at the address given above. If you have concerns about the research or about your rights as a participant, please contact Dr. Brett BuSha, Chair of The College of New Jersey Institutional Review Board (609-771-2452; busha@tcnj.edu).

11. Voluntary participation and the right to discontinue participation without penalty: Your participation in this study is voluntary. You do not have to be in this study if you do not want to be. You have the right to change your mind and leave the study at any time without giving any reason and without penalty. Any new information that may make you change your mind about being in this study will be given to you. You will be given a copy of this consent form to keep. You do not waive any of your legal rights by signing this consent form. You may keep the $10 in compensation even if you choose to withdraw from the study.

12. Conflict of Interest: N/A

13. Additional Information: N/A

14. Consent: *If you sign below, it means that you have read (or have had read to you) the information given in this consent form, and you would like to be a volunteer in this study. You understand that you will receive a copy of this form. You voluntarily choose to participate, but understand that your consent does not take away any legal right in the case of negligence or other legal fault of anyone who is involved in this study. You understand that nothing in this consent form is intended to replace any applicable Federal, State, or Local laws.*

_____

Participant's Name (printed)

_____

Participant's or Authorized Representative's Signature

_____

Date

_____

Principal Investigator's or Authorized Representative's Signature

_____

Date

TCNJ
IRB NUMBER: IRB-2017-0025
IRB APPROVAL DATE: 09/19/2017
IRB EXPIRATION DATE: 09/18/2018